Veeva SiteVault: User Account Management and Training for the Electronic Investigator Site File

Purpose:

This procedure describes the process of requesting and managing user accounts and user security at Virginia Commonwealth University (VCU). Access to Veeva SiteVault, VCU's electronic Investigator Site File [eISF] is based on an individual's need to view, add, change, or delete data or content. Access is based upon a business need, an administrative need, or special circumstances that warrant such access. This procedure outlines actions relating to requesting, establishing, issuing, and suspending user accounts.

Scope:

This procedure applies to activities and essential documents required for the conduct of research at VCU.

Users of this system will be the investigator and investigator delegates, including site administrative and operations personnel. All accounts created for VCU personal will be created using the university's single sign-on (SSO) system which utilizes dual factor authentication.

External users (monitors, inspectors) with responsibility for reviewing research documents will be granted direct access to the eISF system by VCU.

Responsibility:

VCU personnel will be responsible for both performing and complying with this SOP and assuring the appropriate personnel are trained on this SOP.

Definitions:

Application: Veeva SiteVault

Direct Access: Permission to examine, analyze, verify, and reproduce any records and reports that are important to evaluation of a clinical trial. Any party (e.g., domestic and foreign regulatory authorities, sponsor's monitors and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of subjects' identities and sponsor's proprietary information.

eISF: electronic Investigator Site File. The computer system used to house Essential Documents required for the conduct of clinical research by the investigator.

Essential Documents: Those documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements. Often referred to as regulatory documents[1].

External Users: Users of the eISF who are not employees of [SITE NAME] but are granted direct access to the eISF in order to fulfill their responsibilities as outlined by regulatory authorities, contracts, and HIPAA waivers in the capacity of sponsor or inspector.

[1] ICH-GCP E6(R2), 2016. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice. 1.23 Essential Documents (link)

ISF: Investigator Site File. The investigator site file includes all Essential Documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced by the investigator. These documents serve to demonstrate the compliance of the investigator with the standards of Good Clinical Practice and with all applicable regulatory requirements. The ISF does not include the full scope of Trial Master File documents which apply to the sponsor role in research.

Validation of Computer Systems: A process of establishing and documenting that the specified requirements of a computerized system can be consistently fulfilled from design until decommissioning of the system or transition to a new system. The approach to validation should be based on a risk assessment that takes into consideration the intended use of the system and the potential of the system to affect human subject protection and reliability of trial results.[2]

Compliance Statement

VCU uses Veeva SiteVault for the eISF. Veeva SiteVault supports compliance with 21 CFR Part 11 and HIPAA requirements. Documentation of Veeva Vault's compliance with Validation of Computerized Systems can be accessed at the Office of Vice President for Research and Innovation or through Veeva SiteVault's Validation Documents support page section. The system is validated for each change.

Procedures:

User Account Requestor:

- Complete system training via RedCAP
- You will receive an email notification from Veeva when an account has been created
- Log into Veeva SiteVault using your VCU email which will prompt single sign on
- Confirm appropriate access to Veeva SiteVault
- Report inaccurate or inappropriate access to erahelp@vcu.edu immediately
- Ensure passwords are not shared

Site User Role Responsible for account management:

- Receive User Account Request
- Confirm training completion
- Review accuracy of access for requested User Account
- Create new User Account
- Perform periodic access rights review
- Inactivate or suspend user accounts
- Design request processing time to minimize an opportunity for unauthorized access

Site Administrators:

Site administrators have the ability to create or modify all account types within their Veeva Site. VCU is only allowing Site Administrators to create external user accounts (ex: monitor or auditor). Any Site Administrator found to have created or modified an internal user account for another VCU employee will have their account and the other individual's account immediately deactivated by VCU.

References

- ICH E6 (R2): Harmonized Tripartite Guideline for Good Clinical Practice
- FDA E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)
- FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, 2007

[2] ICH-GCP E6(R2), 2016. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice. 1.65 Validation of Computer Systems (link)

- FDA Guidance for Industry: Electronic Source Data in Clinical Investigations, 2013
- FDA Part 11, Electronic Records; Electronic Signatures - Scope and Application, 2003
- CFR Title 21, Part II
- FDA Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 – Questions and Answers, 2023
- Veeva SiteVault Validation Documents

Contact

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Revision/Change History

Date	Version	Change History
02/22/2023	1.0	Initial
03/29/2023	2.0	Added contact information
12/11/2023	3.0	Revised broken links; added statement regarding university use of SSO